

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

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LINDA S. BOBLETZ,

Plaintiff,

3:14-CV-1024 [TJM/DEP]
DOCKET NO:

-against-

VERIFIED COMPLAINT

KARL STORZ ENDOSCOPY-AMERICA, INC.,
KARL STORZ ENDOVISION, INC., KARL STORZ
GMBH & CO. KG and ABC CORPORATIONS 1-10 and
JOHN DOES 1-10 and JANE DOES 1-10,

Defendants.

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Plaintiff, LINDA S. BOBLETZ by her attorneys, ALONSO KRANGLE LLP,
complaining of the defendants, respectfully alleges, upon information and belief, as follows

I. INTRODUCTION

1. This action is a products liability action against KARL STORZ ENDOSCOPY-AMERICA, INC., (STORZ AMERICA), KARL STORZ ENDOVISION, INC. (STORZ ENDOVISION), KARL STORZ GMBH & CO. KG (STORZ) as well as ABC Corporations, 1-10, John Does, 1-10, and/or Jane Does, 1-10, resulting from the use of said defendants' morcellator surgical products. Plaintiff LINDA BOBLETZ, had a surgical procedure performed on her known as a laparoscopic, supracervical hysterectomy with uterine morcellation on or about August 30, 2011 at the United Health Services, Wilson Regional Medical Center 33-57 Harrison Street, Johnson City, NY 13790.

II. JURISDICTION AND VENUE

2. This Court has original jurisdiction pursuant to 28 U.S.C. §1332, as the matter in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs, and is between citizens of different states as plaintiff LINDA BOBLETZ is a resident of the State

of New York and defendants have their principal places of business in the State of California, Commonwealth of Massachusetts and the Federal Republic of Germany, respectively.

3. Venue in the Northern District of New York is proper under 28 U.S.C. §1391(b)(2) as a substantial part of the events or omissions giving rise to the claim occurred in this District.

III. PARTIES

4. Plaintiff LINDA BOBLETZ is an adult individual residing in Endicott, New York.

5. Defendant STORZ AMERICA is a corporation, or other entity, organized and/or existing under the laws of the State of California, and who at all times material and relevant hereto was engaged in the business of manufacturing and/or selling and/or supplying and/or marketing and/or designing and/or distributing minimally invasive surgical products, with a principal place of business at 2151 East Grand Avenue, El Segundo, California 90245-5017.

6. Defendant STORZ ENDOVISION, is a corporation, or other entity, organized and/or existing under the laws of the Commonwealth of Massachusetts, and who at all times was engaged in the business of manufacturing and/or selling and/or supplying and/or marketing and/or designing and/or distributing minimally invasive surgical products, with a principal place of business at 91 Carpenter Hill Road, Charlton, Massachusetts.

7. Defendant STORZ, is a corporation, or other entity, organized and/or existing under the laws of the Federal Republic of Germany, and who at all times was engaged in the business of manufacturing and/or selling and/or supplying and/or marketing and/or designing and/or distributing minimally invasive surgical products, with a principal place of business at Mittelstrasse 8, Tuttingen, Germany 78532.

6. Defendants ABC Corporations, 1-10, are fictitious names, corporations, or other similar entities who were engaged in the business of manufacturing and/or selling and/or supplying and/or marketing and/or designing and/or distributing minimally invasive gynecological surgical products, specifically, the product/s used upon Plaintiff.

7. John Does, 1-10, who were engaged in the business manufacturing and/or selling and/or supplying and/or marketing and/or distributing minimally invasive gynecological surgical products, specifically, the product/s used upon Plaintiff.

8. Jane Does, 1-10, who were engaged in the business manufacturing and/or selling and/or supplying and/or marketing and/or distributing minimally invasive gynecological surgical products, specifically, the product/s used upon Plaintiff.

9. In August 2011, plaintiff LINDA BOBLETZ underwent a surgical procedure known as a laparoscopic supracervical hysterectomy with uterine morcellation at the United Health Services, Wilson Regional Medical Center 33-57 Harrison Street, Johnson City, NY 13790

10. Prior to the Plaintiff's surgery in August, 2011, there was no evidence of disseminated and/or metastatic cancer/disease.

11. Following this procedure, in September 2011 was informed that she had cancer – specifically, leiomyosarcoma.

12. Plaintiff has been undergoing aggressive treatment and therapy since learning of her cancer diagnosis.

13. It is alleged that each and every defendant herein failed to warn about the extent to which there was a possibility of dissemination of an occult uterine leiomyosarcoma throughout the peritoneal cavity.

14. Defendants were each aware of the risks, complications, and/or adverse events associated with their products used for uterine morcellation.

COUNT I – NEGLIGENCE
ON BEHALF OF PLAINTIFF LINDA

15. The paragraphs above are incorporated by reference hereto as if set forth at length.

16. Defendants, STORZ AMERICA, STORZ ENDOVISION, STORZ, ABC Corporations, 1-10, John Does, 1-10, and/or Jane Does, 1-10, (hereafter collectively referred to as "Defendants"), owed a duty to manufacture, compound, label, market, distribute, and supply and/or sell products, including minimally invasive gynecologic products, including products used for uterine morcellation, specifically the Storz Rotocut G1 product manufactured and marketed by defendant STORZ in such a way as to avoid harm to persons upon whom they are used, such as Plaintiff herein, or to refrain from such activities following knowledge and/or constructive knowledge that such product is harmful to persons upon whom it is used.

17. Defendants owed a duty to warn of the hazards and dangers associated with the use of its products, specifically minimally invasive gynecologic products, including products used for uterine morcellation, such as the Storz Rotocut G1 product manufactured and marketed by defendant STORZ for patients such as plaintiff herein, so as to avoid harm.

18. Defendants, acting by and through their authorized divisions, subsidiaries, agents, servants, and employees, were guilty of carelessness, recklessness, negligence, gross negligence and willful, wanton, outrageous and reckless disregard for human life and safety in manufacturing, designing, labeling, marketing, distributing, supplying and/or selling and/or placing into the stream of commerce, minimally invasive gynecologic products, including the Storz Rotocut G1 morcellator, both generally, and in the following particular respects:

- a. failing to conduct adequate and appropriate testing of minimally invasive gynecologic products, such as the Storz Rotocut G1 morcellator, specifically including, but not limited to, products used for uterine morcellation;
- b. putting products used for uterine morcellation such as the Storz Rotocut G1 morcellator on the market without first conducting adequate testing to determine possible side effects;
- c. putting products used for uterine morcellation such as the Storz Rotocut G1 morcellator on the market without adequate testing of its dangers to humans;
- d. failing to recognize the significance of their own and other testing of, and information regarding, products used for uterine morcellation, such as the Storz Rotocut G1 morcellator, which testing evidenced such products potential harm to humans;
- e. failing to respond promptly and appropriately to their own and other testing of, and information regarding products used for uterine morcellation, such as the Storz Rotocut G1 morcellator which indicated such products potential harm to human;
- f. failing to promptly and adequately warn of the potential of the products used for uterine morcellation to be harmful to humans;
- g. failing to promptly and adequately warn of the potential for the metastases of cancer when using products used for uterine morcellation, such as the Rotocut G1 morcellator;
- h. failing to promptly, adequately, and appropriately recommend testing and monitoring of patients upon whom products used for uterine morcellation in light of such products potential harm to humans;
- i. failing to properly, appropriately, and adequately monitor the post-market performance of products used for uterine morcellation and such products effects on patients;

j. concealing from the FDA, National Institutes of Health, the general medical community and/or physicians, their full knowledge and experience regarding the potential that products used for uterine morcellation, specifically the Rotocut G1 morcellator, are harmful to humans;

k. promoting, marketing, advertising and/or selling products used for uterine morcellation, such as the Rotocut G1 morcellator, for use on patients given their knowledge and experience of such products' potential harmful effects;

l. failing to withdraw products used for uterine morcellation from the market, restrict its use and/or warn of such products' potential dangers, given their knowledge of the potential for its harm to humans;

m. failing to fulfill the standard of care required of a reasonable, prudent, minimally invasive gynecological surgical products manufacturer engaged in the manufacture of said products, specifically including products used for uterine morcellation such as the Rotocut G1 morcellator;

n. placing and/or permitting the placement of the products used for uterine morcellation, specifically the Rotocut G1 morcellator into the stream of commerce without warnings of the potential for said products to be harmful to humans and/or without properly warning of said products' dangerousness;

o. failing to disclose to the medical community in an appropriate and timely manner, facts relative to the potential of the products used for uterine morcellation, including the Rotocut G1 morcellator to be harmful to humans;

p. failing to respond or react promptly and appropriately to reports of products used for uterine morcellation causing harm to patients, including the Rotocut G1

morcellator;

q. disregarding the safety of users and consumers of products used for uterine morcellation, including plaintiff herein, under the circumstances by failing adequately to warn of said products' potential harm to humans;

r. disregarding the safety of users and consumers of the products used for uterine morcellation, including plaintiff herein, and/or her physicians' and/or hospital, under the circumstances by failing to withdraw said products from the market and/or restrict their usage;

s. disregarding publicity, government and/or industry studies, information, documentation and recommendations, consumer complaints and reports and/or other information regarding the hazards of the products used for uterine morcellation and their potential harm to humans;

t. failing to exercise reasonable care in informing physicians and/or hospitals using the products used for uterine morcellation about their own knowledge regarding said products' potential harm to humans;

u. failing to remove products used for uterine morcellation from the stream of commerce;

v. failing to test products used for uterine morcellation properly and/or adequately so as to determine its safety for use;

w. promoting the products used for uterine morcellation as safe and/or safer than other comparative methods of lesion removal;

x. promoting the products used for uterine morcellation on websites aimed at creating user and consumer demand;

y. failing to conduct and/or respond to post-marketing surveillance of

complications and injuries.

z. failing to design a morcellation device which required the use of a tissue collection bag to prevent the dissemination of cancer.

19. As a direct and proximate result of the negligent and/or reckless and/or wanton acts and/or omissions of Defendants, Plaintiff suffered serious injuries, and/or financial losses and harm.

WHEREFORE, Plaintiff, LINDA BOBLETZ respectfully requests that this Honorable Court enter judgment in her favor and against, STORZ AMERICA, STORZ ENDOVISION, STORZ, and/or ABC Corporations, 1-10; and/or John Does, 1-10, and/or Jane Does, 1-10, jointly and/or severally, in an amount in excess of \$75,000.00 plus interest, costs and punitive damages, and attorneys' fees to the extent allowed by law.

**COUNT II – STRICT PRODUCTS LIABILITY
ON BEHALF OF LINDA BOBLETZ**

20. The paragraphs above are incorporated by reference hereto as if set forth at length.

21. As a result of the unreasonably dangerous and defective condition of the products used for uterine morcellation, specifically the Rotocut G1 morcellator, which defendants manufactured, designed, labeled, marketed, distributed, supplied and/or sold, and/or placed into the stream of commerce, they are strictly liable to the Plaintiffs for their injuries which they directly and proximately caused, based on the following:

a. failing to properly and adequately design the products used for uterine morcellation, specifically the Rotocut G1 morcellator, in order to prevent the potential spread of malignancy.

22. In addition, the aforesaid incident and Plaintiff's injuries and losses were the

direct and proximate result of Defendants' manufacturing, designing, labeling, marketing, distributing, supplying and/or selling and/or placing into the stream of commerce the products used for uterine morcellation, specifically the Rotocut G1 morcellator without proper and adequate warnings regarding the potential for said products' harm to humans and as otherwise set forth supra, when said defendants knew or should have known of the need for such warnings and/or recommendations.

WHEREFORE, Plaintiff, LINDA BOBLETZ, respectfully requests that this Honorable Court enter judgment in her favor against, STORZ AMERICA, STORZ ENDOVISION, STORZ and/or ABC Corporations, 1-10; and/or John Does, 1-10, and/or Jane Does, 1-10, jointly and/or severally, in an amount in excess of \$75,000.00 plus interest, costs, punitive damages, and attorney's fees to the extent allowed by law.

**COUNT III - BREACH OF EXPRESS WARRANTY
ON BEHALF OF LINDA BOBLETZ**

23. The paragraphs above are incorporated by reference hereto as if set forth at length.

24. In the advertising and marketing of the products used for uterine morcellation, which was directed to both physicians and hospitals and consumers, Defendants warranted that said product or products, including the Rotocut G1 morcellator, were safe for the use, which had the natural tendency to induce physicians and hospitals to use the same for patients and for patients to want to be treated with the same.

25. The aforesaid warranties were breached by defendants in that the Rotocut G1 morcellator products used for uterine morcellation constituted a serious danger to the user.

26. As a direct and proximate result of defendants' breach of express warranty, Plaintiff suffered serious injuries, financial losses and harm.

WHEREFORE, Plaintiff, LINDA BOBLETZ respectfully requests that this Honorable Court enter judgment in her favor and against, STORZ AMERICA, STORZ ENDOVISION, STORZ, and/or ABC Corporations, 1-10; and/or John Does, 1-10, and/or Jane Does, 1-10, jointly and/or severally, in an amount in excess of \$75,000.00 plus interest, costs, punitive damages, and attorney's fees to the extent allowed by law.

**COUNT IV – BREACH OF IMPLIED WARRANTY
ON BEHALF OF LINDA BOBLETZ**

27. The paragraphs above are incorporated by reference hereto as if set forth at length.

28. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Rotocut G1 morcellator used for uterine morcellation.

29. At all relevant times, defendants intended that the products used for uterine morcellation, including the Rotocut G1 morcellator, be used in the manner that the Plaintiff's surgeons in fact used it and Defendants impliedly warranted the product to be of merchantable quality, safe and fit for such use, and was adequately tested.

30. Defendants breached various implied warranties with respect to the products used for uterine morcellation, including:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the products used for uterine morcellation, including the Rotocut G1 morcellator, were safe, and withheld and concealed information about the substantial risks of serious injury and/or death associated with using the products used for uterine morcellation;

b. Defendant represented that the products used for uterine morcellation, including, the Rotocut G1 morcellator, were as safe and/or safer than other alternative surgical approaches that did not include the use of the said products, and concealed information, which demonstrated that said products were not safer than alternatives available on the market; and,

c. Defendants represented that the products used for uterine morcellation, including the Rotocut G1 morcellator, were more efficacious than other alternative surgical approaches and techniques and concealed information, regarding the true efficacy and safety of said products.

31. In reliance upon Defendants' implied warranty, Plaintiff's surgeons used said Rotocut G1 morcellator as prescribed and in the foreseeable manner normally intended, recommended, promoted, instructed, and marketed by Defendant.

32. Defendants breached their implied warranty to Plaintiff in that said Rotocut G1 morcellator used for uterine morcellation was not of merchantable quality, safe and fit for their intended use, or adequately tested.

33. As a direct and proximate consequence of Defendants' breach of implied warranty and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts described herein, the Plaintiff sustained injuries and damages alleged herein including pain and suffering.

WHEREFORE, Plaintiff, LINDA BOBLETZ, respectfully requests that this Honorable Court enter judgment in his favor and against STORZ AMERICA, STORZ ENDOVISION, STORZ and/or ABC Corporations, 1-10; and/or John Does, 1-10, and/or Jane Does, 1-10, jointly and/or severally, in an amount in excess of \$75,000.00 plus interest, costs, punitive damages, and attorney's fees to the extent allowed by law.

COUNT V
FRAUDULENT MISREPRESENTATION AND OMISSION

34. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

35. Defendant, having undertaken design, formulation, testing, manufacture, marketing, sale, and distribution of devices used for uterine morcellation, including the Rotocut G1 morcellator owed a duty to provide accurate and complete information regarding said devices.

36. Prior to Plaintiff LINDA BOBLETZ undergoing her surgery defendants fraudulently misrepresented, that the use of their Rotocut G1 morcellator for uterine morcellation was safe and effective.

37. Defendant had a duty to provide Plaintiff LINDA BOBLETZ, physicians, and other consumers with true and accurate information regarding the devices for uterine morcellation it manufactured, marketed, distributed and sold.

38. Defendant made representations and failed to disclose material facts with the intent to induce consumers, including Plaintiff, LINDA BOBLETZ and the medical community to act in reliance by purchasing and using the Rotocut G1 morcellator sold by defendant.

39. Plaintiff LINDA BOBLETZ and the medical community justifiably relied on Defendant's representations and omissions by purchasing and using the uterine morcellator during Plaintiff's surgery.

40. Defendant's representations and omissions regarding use of its uterine morcellation devices were a direct and proximate cause of LINDA BOBLETZ's injuries.

WHEREFORE, Plaintiff, LINDA BOBLETZ respectfully requests that this Honorable Court enter judgment in his favor and against STORZ AMERICA, STORZ ENDOVISION, STORZ and/or ABC Corporations, 1-10; and/or John Does, 1-10, and/or Jane Does, 1-10, jointly and/or severally, in an amount in excess of \$75,000.00 plus interest, costs, punitive damages, and attorney's fees to the extent allowed by law.

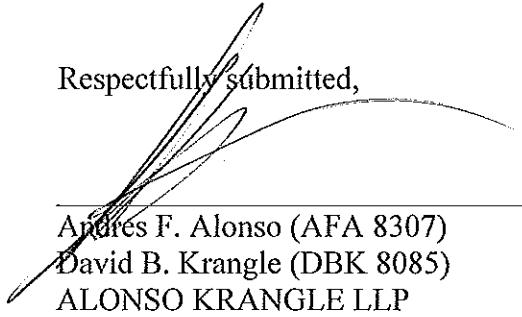
PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief as follows:

1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, society and other non-economic damages in an amount to be determined at trial of this action;
2. Medical expenses and other economic damages in an amount to be determined at trial of this action;
3. Double or triple damages as allowed by law;
4. Restitution and disgorgement of profits;
5. Reasonable attorneys' fees;
6. Punitive damages;
7. The costs of these proceedings; and
8. Such other and further relief as this Court deems just and proper.

Dated: Melville, New York
August 18, 2014

Respectfully submitted,



Andres F. Alonso (AFA 8307)
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ATTORNEYS VERIFICATION

STATE OF NEW YORK)
: ss:
COUNTY OF NASSAU)

Andres F. Alonso, an attorney and counselor at law, duly admitted to practice in the Courts of the State of New York, affirms the following to be true under penalties of perjury:

I am a member/associate of the firm **ALONSO KRANGLE LLP** attorneys for the plaintiff(s) herein.

I have read the foregoing COMPLAINT and know the contents thereof. Upon information and belief, I believe the matters alleged therein to be true.

The source of your deponent's information and the grounds of my belief are communications, papers, reports and investigations contained in my file.

The reason this verification is made by deponent and not by plaintiff(s) is that plaintiff(s) reside in a county other than the one in which your deponent's office is maintained.

Dated: Melville, New York
August 18, 2014

Andres E. Alonso